DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
S4402d

60 8th Street, N.E.
Atlanta, Georgia 30309

November 6, 2003

VIA FEDERAL EXPRESS

William E. Barclift, President
Quality Seafood Company, Inc.
177 Knobbs Creek Drive
Elizabeth City, NC 27909

Warning Letter
04-ATL-02

Dear Mr. Barclift:

On September 10 & 9, 2003, FDA conducted an inspection of your seafood repacking facility located at Elizabeth City, North Carolina. During that inspection, our investigators documented serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your fresh, histamine-forming fish is adulterated, in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The deviation of concern is as follows:

> You must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for scombroid fish to control the histamine formation hazard.

We may take further action if you do not promptly correct these violations. For instance, we may recommend that the United States bring a legal action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as copies of HACCP plans, and HACCP monitoring

records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Mary Woleske

Mary H. Woleske, Director
Atlanta District